o · 10/535.024 SC&C-112US

Appln. No.: 10/535,024

Amendment Dated March 20, 2009

Reply to Final Office Action of November 20, 2008

REMARKS

This application contains claims 1-112, the status of which is as follows:

(a) Claims 25-31, 33-34, 36, 66-72, and 74-100 were previously presented.

(b) Claims 35, 37-40, 43-45, and 48 are as originally filed.

(c) Claims 1-24, 32, 49-65, and 73 were previously canceled without prejudice.

(d) Claims 41-42 and 46-47 have been currently amended.

(e) Claims 101-112 are new.

No new matter has been added.

Allowable subject matter

Applicants thank the Examiner for finding that claims 33, 74, and 81-100 are allowed.

Applicants respectfully suggest that new claims 103-105, which are dependent on allowed claim 33, and new claims 106-108, which are dependent on allowed claim 74, are allowable as well.

Claim rejections under 35 U.S.C. 103

Claims 25-31, 34-39, 43, 45, 48, 66-72, and 75-80 were rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,526,318 to Ansarinia in view of Seylaz et al., "Effect of Stimulation of the Sphenopalatine Ganglion on Cortical Blood Flow in the Rat." Claims 40 and 44 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ansarinia and Seylaz et al. and further in view of US Patent Application Publication 2002/0077687 to Ahn. Claims 41, 42, 46, and 47 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ansarinia and Seylaz et al. and further in view of US Patent Application Publication 2004/0138097 to Guyuron.

Applicants respectfully traverse these rejections. The Examiner argued that independent claims 25 and 26 are obvious "since the ordinary artisan would be well aware of the most direct and effective route to the desired stimulation site" (¶2 of the office action dated June 12, 2008, referred to in ¶1 of the present office action). Although the ordinary artisan might be aware of the most direct and effective route to a desired stimulation site,

SC&C-112US

Appln. No.: 10/535,024

Amendment Dated March 20, 2009

Reply to Final Office Action of November 20, 2008

Applicants submit that the ordinary artisan would not have considered the recited transpalatine approach to be such a route. Applicants therefore respectfully disagree with this rejection, and believe that the ordinary artisan would not have considered the recited transpalatine approach as the most direct and effective route for implanting a treatment stimulation device at the SPG. At the filing date of the present application, the greater palatine canal was not an obvious path for implanting a stimulation device at least because:

- (A) passing a stimulation device through the canal presents substantial challenges, including: (a) the small diameter of the canal, which is too narrow to readily allow the passage of a stimulation device, and (b) the presence of the greater palatine neurovascular bundle within the canal, which occupies a fairly large portion of the canal, and should not be damaged when passing the stimulation device through the canal; and
- (B) the canal does not terminate near an external surface of the patient's body, in order to provide convenient access to an electrode lead for connection to a power source. In contrast, Ansarinia's surgical technique provides such access (see col. 12, lines 40-61 of Ansarinia).

Applicants' invention involved both recognizing the potential of the transpalatine approach for implanting a stimulator, and developing a surgical procedure and stimulator that overcomes the challenges presented by this route. With respect to point (A), for example, the present application describes in detail techniques for widening the canal (to about 2 mm, typically) (e.g., p. 26, line 19 – p. 27, line 26). With respect to point (B), the recited stimulation device may comprise a wireless receiver implanted against the hard palate (as described, for example, on p. 22, line 29 – p. 23, line 3), to obviate the need for external access to electrode leads hanging out of the patient's mouth.

Applicants thus respectfully submit that independent claims 25 and 26 are not obvious over Ansarinia in view of Seylaz et al. Dependent claims 27-31, 34-48, 66-72, and 75-80 are also in a condition for allowance, being of narrower scope than the allowable claims from which they directly or indirectly depend.

In addition, Applicants respectfully submit that dependent claims 41 and 46 are independently patentable. Although periosteal elevators, as taught for example by Guyuron, are well known, Applicants submit that widening the greater palatine canal to facilitate passage of a stimulator therethrough is a novel and non-obvious use of such

SC&C-112US Appln. No.: 10/535,024

Amendment Dated March 20, 2009

Reply to Final Office Action of November 20, 2008

elevators, which is neither taught nor suggested by Guyuron. Applicants have amended claims 41 and 46 to recite only the widening of the canal, and have added new claims 101 and 102 that recite the use of the elevators. Conforming amendments have been made to claims 42 and 47, and new claims 103 and 106 have been added that recite this widening technique for allowed independent claims 33 and 74, respectively.

As discussed above, Applicants respectfully submit that new claims 103-105, which are dependent on allowed claim 33, and new claims 106-108, which are dependent on allowed claim 74, are allowable as well.

Support for new claims 104, 105, and 107-112 is found, for example, in the description of Figs. 15A and 15B, in the second and third full paragraphs on page 27.

Applicants submit the amendments and remarks presented hereinabove to be fully responsive to all of the grounds of rejection raised by the Examiner. In view of these amendments and remarks, Applicants respectfully submit that all of the claims in the present application are now in order for allowance. Notice to this effect is respectfully requested.

Respectfully submitted,

RatnerPrestia /

Jacques L. Etkowicz, Reg. No. 41,738

Attorney for Applicants

JLE/kpc

Dated: March 20, 2009

P.O. Box 980 Valley Forge, PA 19482 (610) 407-0700

The Director is hereby authorized to charge or credit Deposit Account No. 18-0350 for any additional fees, or any underpayment or credit for overpayment in connection herewith.